BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 536 164 B1**

(12) # EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification:
09.03.94 Bulletin 94/10

(51) Int. Cl.[5]: **A61F 2/06**

(21) Application number: **91910030.5**

(22) Date of filing: **25.04.91**

(86) International application number:
PCT/US91/02854

(87) International publication number:
WO 92/00043 09.01.92 Gazette 92/02

(54) **SELF-EXPANDING PROSTHESIS HAVING STABLE AXIAL LENGTH.**

(30) Priority: **28.06.90 US 544923**

(43) Date of publication of application:
14.04.93 Bulletin 93/15

(45) Publication of the grant of the patent:
09.03.94 Bulletin 94/10

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(56) References cited:
EP-A- 0 177 330
EP-A- 0 183 372
EP-A- 0 335 341
EP-A- 0 421 729
WO-A-83/00997

(56) References cited:
WO-A-89/08433
DE-B- 1 766 921
FR-A- 2 409 747
GB-A- 2 189 150
US-A- 3 623 484
US-A- 4 681 110

(73) Proprietor: **SCHNEIDER (USA) INC.,**
5905 Nathan Lane
Plymouth, Minnesota 55442 (US)

(72) Inventor: **PORTER, Christopher, H.**
19756 N.E. 127th Place
Woodenville, WA 98072 (US)

(74) Representative: **Bradbrook, Geoffrey William (GB) et al**
PFIZER Limited
GB-Sandwich, Kent CT13 9NJ (GB)

EP 0 536 164 B1

D s rlptlon

Technical Field

The present invention relates to body implantable devices, and more particularly to prostheses and grafts intended for long-term or permanent fixation in body cavities.

Background Art

A wide variety of patient treatment and diagnostic procedures involve the use of devices inserted into the body of the patient, with some of these devices being permanently implanted. Among these devices are prostheses or grafts for transluminal implantation, for example as disclosed in U. S. Patent No. 4,655,771 (Wallsten). The prosthesis described in Wallsten is a flexible tubular braided structure formed of helically wound thread elements. Gripping members at opposite ends of the prosthesis initially secure it to a catheter, with the proximal gripping member being movable distally to give the prosthesis the shape of a balloon. In deployment, the gripping members and catheter are removed, leaving the prosthesis to assume a substantially cylindrical shape as it slightly expands and substantially conforms to a blood vessel wall or other tissue. Another prosthesis is disclosed in U. S. Patent No. 4,681,110 (Wiktor). A flexible tubular liner, constructed of braided strands of a flexible plastic, is insertable into the aorta, whereupon it self-expands against an aneurysm to direct blood flow past the aneurysm. The braided stents of Wallsten and Wiktor axially contract as they radially expand.

Another elastic stent is shown in U. S. Patent No. 4,830,003 (Wolff et al). The stent includes a series of generally longitudinal wires welded together in pairs, with the wires in each pair then bent into a "V" shape. Like the braided stents, this stent shortens axially as it radially expands.

Prostheses also have been constructed of plastically deformable materials. U. S. Patent No. 4,733,665 (Palmaz) discloses intraluminal vascular grafts radially expanded using angioplasty balloons. The grafts are wire mesh tubes, and axially shorten as they radially expand. U. S. Patent No. 4,800,882 (Gianturco) features a stent formed of wire, including a plurality of serpentine bends to form opposed loops. A balloon is inflated to radially expand the stent, without substantial axial shortening.

Yet another approach to prosthesis design is shown in U. S. Patent No. 3,868,956 (Alfidi et al). Alfidi et al discloses a strainer or screen with a plurality f generally l ngitudinal wires, bound tog ther by a cylindrical sle v . Th wires are deformabl into a longitudinal, straight-line configurati n for implantation. Onc implanted, the device is heated. Due to th r covery prop rty of th metal forming the wires (.g. nitinol alloy), heating causes the wir s t flare radially outward at th opposite ends, thus t secur th device at th desired location. A stent including m ans for maintaining a constant axial length in spite f radial expansion or contraction, is disclosed in U. S. Patent No. 4,553,545 (Maass et al), as a prosthesis in the form of a helical coil spring. In one embodiment, a constant axial length of the spring is maintained, with opposite ends of the spring rotated relative to one another to change the spring pitch and radius. An alternative approach involves maintaining a constant pitch over a given section of a spring, by providing spring material to a "constant length" section from a more compressed section of the spring. In each case, the spring preferably is elastic, with a memory favoring the radially expanded configuration.

A self-expanding stent or prosthesis often is preferred over a plastically deformed device. Resilient stents can be deployed without dilatation balloons or other stent expanding means. A self-expanding stent can be preselected in accordance with the diameter of the blood vessel or other fixation site. While deployment requires skill in positioning the prosthesis, the added skill of properly dilating the balloon to plastically expand a prosthesis to a selected diameter is not required. Also, the self-expanding device remains at least slightly compressed after fixation, and thus has a restoring force which facilitates acute fixation. By contrast, the plastically expanded stent must rely on the restoring force of deformed tissue, or on hooks, barbs or other independent fixation means.

Further advantages arise from constructing the prosthesis of multiple, braided and helically wound strands or filaments as in the aforementioned Wallsten patent. The filaments themselves have a restoring force which causes the filaments to bear against tissue walls of the body cavity in which the stent is fixed, thus maintaining the cavity open. At the same time there is sufficient space between adjacent filaments to promote embedding of the stent into the tissue, and fibrotic growth to enhance long-term fixation. A further advantage of this construction .is that it enables a substantial radial contraction of the prosthesis during deployment, for example to as little as about one-fourth of the normal diameter (the diameter in the relaxed state, i.e. when subject to no external forces). This facilitates deployment of the prosthesis through narrow vessels or other constrictions on the way to the point of fixation.

At the same time, a substantial axial elongation accompanies the radial contraction. There is a substantial axial contraction or shortening as the stent self expands, once free of its radial constraint. Thus, th re is a rubbing or scraping action axially along tissu as th radially expanding st nt also axially shortens. Should tissue at th fixation area furth r yi ld to radial prosthesis expansion in the l ng r term, such xpansion caus s furth r axial short ning and wiping

action, and presents further risk of injury to tissue. A further drawback is that a stent during its fixation may radially expand more than expected, retaining less than the intended or minimum necessary axial length. Likewise, a plastically deformable stent may require more than the anticipated radial expansion and axial shortening.

Therefore, it is an object of the present invention to provide a prosthesis of open weave, helical and braided construction capable of substantially maintaining its axial length as it radially self-expands.

Another object is to provide a radially expanding tubular stent comprised of at least two stent segments, with an area of overlap of the sections variable in axial length to maintain a consistent axial separation between non-overlapping ends of the stent.

Yet another object is to provide a stent with a medial portion variable in axial length, in combination with means at the opposite end portions of the stent for fixing the stent to bodily tissue, such that the bodily tissue maintains a substantially constant axial separation of the two end portions during any radial expansion or contraction of the stent.

Disclosure of Invention

To achieve these and other objects, there is provided a body implantable device, including coaxial first and second open weave stent segments slidably engaged to form a stent. The stent segments are engaged along respective concentric first and second axially inward portions overlapping one another to form a medial region of the stent. Further, the stent segments include opposite non-overlapping first and second axially outward regions with respective and opposite first and second ends of the stent. The stent segments, at least along the axially inward portions, have a predetermined first diameter and a predetermined first axial length. The stent segments are radially compressible to a second diameter less than the first diameter and to a second axial length longer than the first axial length, to facilitate an axial insertion of the stent into a body cavity for delivery to a selected location along the body cavity and subsequent fixation of the stent to a cavity wall segment defining the body cavity. During its fixation, the stent radially expands. The first and second axially inward portions slide relative to one another to reduce the axial length of the medial region during the radial expansion under positive fixation of said first and second ends. Thus the stent maintains a substantially constant axial length during radial expansion.

A preferred approach uses means for fixing the outward ends of a self-expanding stent, e.g. respective first and second flared outer end portions along the axially outward regions of the stent. The first and second ends have diameters greater than the first diameter when the stent is in the relaxed state, and when compressed to have a greater restoring force against the cavity wall segment, as compared to the remainder of the stent. The end diameters should be greater than the medial region diameter by five percent or more, ensuring a substantial difference in restoring force for a relatively constant diameter of the cavity along the tissue wall segment.

Alternatively, the outer end portion of each stent segment can have the same diameter as the medial region, but be composed of larger diameter filaments, added windings of filaments or otherwise have increased stiffness or resistance to radial contraction as compared to the medial region. Yet another alternative is to provide fixation elements, for example hooks, at the opposite ends of the stent.

In combination with positive fixation of the stent ends, a substantial medial overlapping region is provided when the stent segments are in a radially compressed or delivery configuration. For example, the overlapping region may comprise three-fourths or more of the axial length of the compressed stent. Then, upon deployment of the stent, both stent segments radially expand and axially shorten. With the outer ends of the stent fixed, the axial shortening occurs only along the medial region, substantially shortening the region of overlap but maintaining the desired axial separation of the opposite stent ends.

An open weave of braided, helically wound strands or filaments is the preferred structure of the tubular stent. The open weave structure enables substantial self-expansion in the stent, for example to a fixation diameter at least three times the diameter during delivery. This of course results in a substantial corresponding axial shortening in each of the stent segments, but due to the overlapping medial region of the stent, the overall axial length remains virtually constant.

A pliable catheter is a suitable apparatus for delivery and deployment of the stent. More particularly, a pliable sheath can surround at least the distal end portion of the catheter and extend beyond the distal tip to surround the stent segments as well, maintaining them in a radially compressed delivery configuration. The catheter can be provided with a lumen, through which a guide wire may be inserted to facilitate travel of the catheter and compressed stent through blood vessels or other body cavities to the fixation area. Once the catheter is inserted properly to position the stent at the desired fixation point, the outer sheath is withdrawn proximally, with the stent abutting the catheter and thus secured against proximal travel with the sheath. The distal portion of the stent self-expands first, and in expanding against tissue, secures the stent segment against proximal travel. With one end of the stent constrained by tissue and the opposite end constrained by a stationary catheter, the axial length of the stent remains substantially constant. Axial shortening of the stent seg-

ments, which accompanies their radial expansion, tends to diminish the length of th m dial region and leav the overall axial l ngth unaffected.

Following fixation, furth r yielding f the tissue segment can result in further radial expansion of the stent. However, with the opposite ends of the stent secure, any axial shortening of the stent segments again affects only the medial overlapping region. Thus, the advantages of the open weave construction are retained, without an undesirable shortening of the stent as it radially self-expands.

Brief Description of Drawings

For a further understanding of the above and other features and advantages, reference is made to the following detailed description and the drawings, in which:

Figure 1 is a side elevation of a body implantable device constructed in accordance with the present invention;

Figure 2 is a side sectional view of a catheter and sheath retaining the implantable device in a radially compressed condition;

Figure 3 is an end view of the device, catheter and sheath;

Figure 4 is a side sectional view showing deployment of the device within a body cavity;

Figure 5 is a side view of the device fixated within the cavity;

Figure 6 is a side elevation of an alternative embodiment device in the relaxed or fully radially expanded condition;

Figure 7 is a side elevation showing yet another alternative device in the expanded or relaxed condition;

Figure 8 is a side elevation illustrating a further alternative device in a radially compressed state;

Figure 9 is a side elevation of the device of Figure 8 in the expanded condition;

Figure 10 is a side elevation showing yet another alternative device, in a radially compressed condition; and

Figure 11 is a side elevation of the device of Figure 10 in the radially expanded condition.

Modes for Carrying Out the Invention

Turning now to the drawings, there is shown in Figure 1 a body implantable prosthesis or stent 16. Stent 16 has an open mesh or weave construction, formed of helically wound and braided strands or filaments 18 of a resilient material, for example a body compatible stainless st l or an lastomer, .g. polypropylene, polyurethane, polysulfon or a poly ster.

Stent 16 includes coaxial proximal and distal st nt segments 20 and 22. A medial region 24 is form d by th overlapping of resp ctive axially inward portions of stent segm nts 20 and 22. Axially outward, non- verlapping portions of th st nt segments are indicat d at 30 and 32, resp ctively. At opposit ends of the stent ar flared ends 34 and 36, each having a greater radius than the nominal radius over the majority of the stent length. As is later explained, flared ends 34 and 36 provide a fixation feature useful to maintain a constant overall axial length in stent 16, even while stent segments 20 and 22 radially self-expand and axially contract during fixation.

In Figure 1, stent 16 is shown in its relaxed condition, with no external forces applied to radially contract the stent. Stent 16 is self-expanding in the sense that when not subject to external forces, it assumes a diameter much larger than the diameter illustrated in Figures 2 and 3. In these figures, the stent is elastically deformed and maintained in a radially reduced configuration by a pliable, dielectric sheath 38 surrounding the stent.

An elongate and pliable catheter 40, of which just the distal end region is shown in Figure 2, includes a distal tip 42 which abuts the proximal end of the stent. The proximal portion of sheath 38 surrounds the distal end region of the catheter. Catheter 40 has a central lumen 44 open to tip 42 and running the length of the catheter, to permit delivery of a drug, in liquid form, to the catheter distal tip from a supply at the proximal end of the catheter. Lumen 44 further enables the use of a guide wire (not shown) which can be intravenously inserted, by its distal end to the desired point of fixation for stent 16. With the guide wire in place, catheter 40, stent 16 and sheath 38 are positioned to surround the proximal end of the guide wire with the guide wire contained within lumen 44. Then, the catheter, sheath and stent are moved distally or advanced, directed by the guide wire to the fixation location, whereupon the guide wire can be withdrawn.

Sheath 38 preferably is constructed of silicone rubber or other suitable biocompatible material, and surrounds the stent and catheter at least along the catheter distal end region, or along the full length of the catheter if desired. Sheath 38 preferably is thin to facilitate intravascular insertion of the catheter, sheath and stent, yet is sufficiently thick to maintain stent 16 in a reduced radius or delivery configuration against the restoring force of strands 18. The outside diameter of the assembly including the catheter, stent and sheath is approximately 2.3 millimeters.

Stent 16 is particularly well suited for use as a prosthesis or graft in a blood vessel or other body cavity. One advantageous use of the stent occurs in connection with percutaneous transluminal coronary angioplasty (PTCA) procedures. Whil such procedures afford significantly reduced cost and risk as compar d t coronary bypass operations, acute closure and recurrence of stenosis ar significant problems in up to about thirty p rcent of constricted or

blocked passages opened by ballo n angi plasty. The fixation of stent 16 within a blood v ss l along a previously occluded region tends to ke p this region permanently pen.

Fixation of stent 16, within a blood vessel 46 having a tissue wall segment 48, begins with intravascular insertion of the stent, catheter and sheath in the delivery configuration shown in Figures 2 and 3. The reduced radius facilitates insertion of this assembly through blood vessel 46 until stent 16 reaches a predetermined fixation location along the blood vessel. Once the proper positioning of the stent is confirmed, e.g. through use of one or more radiopaque markings on the stent, sheath or catheter, sheath 38 is moved proximally with respect to catheter 40.

With distal tip 42 abutting stent 16, the catheter prevents the stent from traveling proximally with sheath 38 as the sheath is withdrawn. Thus, as seen from Figure 4, stent 16 becomes free of sheath 38 over an increasing distal portion of its axial length. As each of stent segments 20 and 22 becomes free, it radially self-expands until contacting tissue wall segment 48, then undergoes slightly further radial expansion until the tendency to radially expand is counterbalanced by the restoring force exerted radially inward by the tissue wall segment. At the equilibrium condition, shown in Figure 5, stent is not fully radially expanded to the relaxed configuration shown in Figure 1, and thus applies a restoring force which tends to maintain the stent at the fixation position within vessel 46.

A salient feature of the present invention is the concentric and slidable mounting of stent segments 20 and 22 in combination with the fixation provided by flared ends 34 and 36. During initial withdrawal of sheath 38, the distal flared end 36 is the first to encounter tissue wall segment 48. Due to its larger nominal (relaxed state) diameter, flared end 36 tends to radially expand somewhat more than the remainder of axially outward portion 32 of this segment, and applies comparatively greater restoring force in the radially outward direction against the tissue wall segment. Accordingly, the axial shortening of distal stent segment 22 which accompanies radial expansion, e.g. from a length of 100 mm when delivered to a fixation length of 50 mm, occurs almost entirely by travel of axially inward portion 24, distally or rightwardly as viewed in Figure 4. The slidable engagement of segments 20 and 22 permits such distal travel while proximal segment 20 remains substantially fixed relative to catheter 40.

As sheath 38 is further withdrawn, proximal segment 20 likewise radially expands and axially shortens. As illustrat d in Figure 4, much of axially utward portion 30 of segm nt 20 r mains radially compressed within sh ath 38, and thus is held fixed with r spect to th cath ter. Consequently, the axial contraction of proximal st nt segment 20 during radial xpansion occurs almost ntirely by virtue of proximal travel of its axially inward portion. This f course involves further sliding of the stent s gm nts relative to one anoth r, and further r duc s the axial length of medial overlapping region 24.

As seen from Figures 2 and 5, the total axial length of stent 16, designated "L", is substantially the same whether the stent is in the deployment state, or the radially expanded to equilibrium or fixation. Proximal stent segment 20 and distal stent segment 22 are each substantially shorter in equilibrium. However, virtually all of the reduction in axial length is reflected in the substantially reduced length of medial overlapping region 24, which accounts for more than three-fourths of the total stent length in Figure 2, and only about one-fifth of the overall stent length in Figure 5.

Eventually, fixation of stent 16 becomes permanent by virtue of the embedding of strands 18 into tissue wall segment 48, and fibrotic growth of tissue between and around strands to anchor the stent. This type of fixation occurs over a period of weeks, and in the intervening time, tissue wall segment 48 may yield to allow further radial expansion of a stent, and further axial shortening of stent segments 20 and 22. The axial length "L" remains substantially constant nonetheless, as this further axial contraction is again reflected in a further shortening of the medial overlapping region. Axial contraction occurs along the medial region, since flared ends 34 and 36 continue to exert a comparatively greater restoring force against the tissue, thus more securely anchoring the ends as compared to the central portions of the stent. Thus, the overall length of the stent is maintained not only during and immediately after fixation, but in the interim until fibrosis permanently secures the stent.

Figure 6 shows an alternative embodiment stent 52, again with concentric and slidably connected proximal and distal stent segments as indicated at 54 and 56. Axially inward portions of the stent segments overlap to form a medial region 58. Stent 52 has an open mesh or weave construction, formed of helically wound and braided filaments 60.

Stent 52, illustrated in its relaxed or unstressed state, does not include radially outward flares at its opposite ends. In lieu of flared ends, each of stent segments 54 and 56 includes at its axially outward end a plurality of reinforcing strands 62 connected to the braided filaments 60, thus to create respective proximal and distal reinforced end regions 64 and 66. The reinforcing strands 62 can, but need not, be of the same construction as the base filaments. In either event, the reinforcement strands lend further elastic resistance to radial compression, such that a given elastic radial compression of stent 52 r quir s a greater f rce at reinforced nd regions 64 and 66 as compar d to the force r quir d between thes regions.

Stent 52 can be deploy d in th manner descri-

bed above in connecti n with stent 16. F llowing proper positioning of the stent within a blood vessel or other body cavity, a surrounding sheath similar t sheath 38 is withdrawn proximally from its surrounding relation with stent 52, allowing the stent to radially self-expand into contact with the tissue forming the cavity. Again, stent 52 is selected to have a nominal diameter (in the relaxed state) greater than the diameter of the body cavity, so that base filaments 60 and reinforcement strands 62 engage the tissue before full expansion, and are contained short of full expansion by body tissue, for an equilibrium of the restoring force in the stent and the oppositely directed restoring force in the body tissue. With the stent in equilibrium (as shown in Figure 5 in connection with stent 16), reinforced end regions 64 and 66 may or may not flare slightly radially outward from the remainder of the stent. In either event, the restoring force at the reinforced end regions is greater than the restoring force along the remainder of the stent length. Accordingly, the opposite ends of stent 52 tend to remain secure in their axial positioning relative to the body tissue, with axial contraction occurring as substantial reduction in the length of medial region 58.

Figure 7 illustrates yet another approach to preserving the axial length of the stent, in this case, a plurality of fixation hooks 70 at the opposite ends of a stent 72 having a slidably interconnected and coaxial proximal and distal stent segments 74 and 76. Fixation hooks 70 present some risk of injury and thus are more limited in their application than the fixation alternatives previously discussed. Nonetheless, hooks 70 provide a positive and immediate fixation of stent 72 within a cavity at the opposite stent ends. Subsequent radial expansion and axial contraction of stent segments 74 and 76 serves to reduce the length of a medial region 78, preserving the overall length of the stent.

Figures 8 and 9 illustrate a further embodiment stent or prosthesis 80 including a proximal segment 82, a distal segment 84 and a center segment 86 slidably engaged with the proximal and distal segments. All three segments of prosthesis 80 have the previously described open mesh or weave construction of braided filaments. Stent 80 thus includes two overlapping regions intermediate its proximal and distal ends 88 and 90, namely a proximal intermediate region 92 and a distal intermediate region 94. While center segment 86 is shown with a smaller radius than the other segments for convenience of illustration, all segments preferably have substantially the same radius.

Figure 9 illustrates stent 80 in the relaxed or radially expanded state. Each of segments 82, 84 and 86 has a r duced axial dimension as well as a larger radius. Non theless, the axial distanc b tw n proximal nd 88 and distal nd 90 remains about th same, with virtually all of th axial contraction refl ct-ed in th substantially reduced axial dimensions of intermediate v rlapping r gions 92 and 94.

Prosthesis 80 can b depl y d in th manner described abov in connection with other mbodim nts. Following the desired positioning of the prosthesis within a blood vessel or other body cavity, a surrounding sheath is withdrawn slidably or folded back from a surrounding relation to the prosthesis, permitting it to radially self-expand into contact with a tissue wall segment forming the cavity (not shown). Of course, the diameter of the cavity should be less than the normal or radially expanded diameter of the prosthesis. Prosthesis 80 does not utilize any special end fixation structure such as the earlier described hooks, reinforced ends or flared ends. Rather, the prosthesis is positioned by virtue of the self-expansion and restoring force of the segments, to maintain their relative positions, particularly during their deployment and release from a sheath or the like, but also after fixation. It should be noted that this approach is suitable for the two-segment stents earlier described, although some type of end fixation means facilitates maintaining a constant axial length of the stent. If desired, a fixation structure can be provided at ends 88 and 90.

Figures 10 and 11 illustrate yet another embodiment stent 96 including proximal and distal segments 98 and 100, slidably engaged and overlapping along.a medial region 102. A strand or wire 104 runs parallel to stent 96 and is secured at points 106 and 108 near proximal and distal ends 110 and 112, respectively. Wire 104 is sufficiently flexible to bend along with stent segments 98 and 100 during delivery of the stent to the point of fixation. Yet the wire is stiff and substantially inextensible in the axial direction. Consequently wire 104 maintains a constant axial separation of proximal end 110 and distal end 112, whether stent segments 98 and 100 are radially confined as shown in Figure 10 or radially expanded as seen in Figure 11. With wire 104 positively determining the total length of stent 96, all of the axial contraction of stent segments 98 and 100 is reflected in the reduction of medial overlapping region 102. While the provision and securement of one or more wires 104 add to the cost of stent 96 as compared to other embodiments, the wire ensures that the stent length remains constant, regardless of the amount of radial expansion during fixation.

The above embodiments all feature an open weave or braided construction of resilient filaments for a self-expanding stent or prosthesis. As an alternative, the stents can be constructed of plastically deformable strands. Such stents are delivered in a reduced-radius configuration, and after positioning, are radially expanded by dilating a catheter balloon or th lik , .g. as in th aforem ntion d Palmaz patent. Moreover, while the disclos d embodiments are employ d in blood v ss ls, it is to b appr ciated that

these stent designs are suited for other body cavities as well, e.g. the urethra, biliary tree or tracheobronchial tree. Regardless of whether hooks, reinforcing strands or outwardly flared end portions are employed for outer end fixation, the full axial length of the stent is maintained substantially constant, unaffected by radial expansion and accompanying axial contraction of the engaged stent segments. Accordingly, upon deployment and in the ensuing weeks after fixation, the functional advantages of a helically wound, braided filament design are achieved without the disadvantages associated with axial shortening.

Claims

1. A device for fixation in a body cavity, comprising:
   a stent (16) including generally tubular and coaxial first and second open weave stent segments (20, 22) slidably engaged along respective first and second axially inward portions overlapping one another to form a medial region (24) of the stent (16), said stent segments (20, 22) further including respective non-overlapping first and second axially outward regions (30, 32) including respective and opposite first and second ends (34, 36) of the stent (16);
   said stent segments (20, 22), at least along said axially inward portions, having a predetermined first diameter and a predetermined first axial length, said stent segments (20, 22) being radially compressible to a second diameter less than said first diameter and to a second axial length longer than said first axial length, to facilitate an axial insertion of said stent (16) into a body cavity for delivery to a selected location therealong and subsequent fixation of the stent (16) within the cavity by effecting an engagement of the stent segments (20, 22) with a tissue wall segment defining said body cavity; and
   wherein said first and second axially inward portions are capable of sliding relative to one another to reduce the axial length of said medial region (24) as said stent segments (20, 22) radially expand into said engagement under positive fixation of said first and second ends (34,36), thus to maintain a substantially constant axial length of said stent (16) during said radial expansion.

2. The device of Claim 1 wherein:
   each of said stent segments (20, 22) is an open weave construction of helically wound filaments (18) of a resilient, body-compatible material.

3. The device of Claim 2 further including:
   a means for fixing said first and second ends (34, 36) to said tissue wall segment.

4. The device of Claim 3 wherein:
   said stent segments (20, 22) are flexible and have said predetermined first diameter and first axial length when not subject to external force, and are elastically compressible to said second diameter.

5. The device of Claim 4 wherein:
   said fixing means comprises first and second flared outer end portions of said first and second axially outward regions (30, 32), respectively, whereby said first and second ends (34, 36) have diameters greater than said first diameter when the stent (16) is in the relaxed state.

6. The device of Claim 5 wherein:
   the diameters of said first and second ends (34, 36) are greater than said first diameter by at least five percent.

7. The device of Claim 6 wherein:
   the axial length of each of said flared outer end portions is less than one-third of the axial length of its associated one of said stent segments (20, 22).

8. The device of Claim 4 wherein:
   said fixing means comprises elastic reinforcing strands connected to said filaments along first and second outer end portions including said first and second ends (34, 36), respectively.

9. The device of Claim 3 wherein:
   said fixing means comprises first and second pluralities of fixation hooks mounted to the stent (16) at said first and second ends (34, 36), respectively.

10. The device of Claim 1 further including:
    an elongate, flexible and substantially inextensible member running axially and connected to said first and second stent segments (20, 22) proximate said first and second ends (34, 36), for maintaining the axial length of the stent (16) constant during said radial expansion.

Patentansprüche

1. Vorrichtung zur Fixierung in einem Körperhohlraum, umfassend: einen Spreizkörper (16) mit allgemein rohrförmigen und k axialen ersten und zweiten Spreizkörperabschnitten (20, 22) in offener Wabart (open weave), die in gleitendem Eingriff entlang einem ersten bzw. zweiten axial innen liegenden Teilstehen, wobei die Teile in-

ander unter Bildung eines mittleren Bereichs (24) des Spreizkörpers (16) überlappen, und wob i die Spreizkörp rabschnitte (20, 22) weiterhin nicht überlapp nd inen ersten bzw. inen zw i- ten axial außen liegenden Bereich (30, 32) aufweisen, die gegenüberliegend ein erstes bzw. ein zweites Ende (34, 36) des Spreizkörpers (16) enthalten;
wobei die Spreizkörperabschnitte (20, 22) zumindest entlang den axial innen liegenden Teilen einen vorgegebenen ersten Durchmesser und eine vorgegebene erste axiale Länge haben, und radial bis auf einen zweiten Durchmesser, der kleiner ist als der erste Durchmesser, und auf eine zweite axiale Länge, die größer ist als die erste axiale Länge, zusammendrückbar sind, um ein axiales Einsetzen des Spreizkörpers (16) in einen Körperhohlraum zum Verbringen an eine ausgewählte Stelle entlang dem Hohlraum und zum anschließenden Fixieren des Spreizkörpers (16) innerhalb des Hohlraums durch Bewirken eines Angriffs der Spreizkörperabschnitte (20, 22) an einem Gewebewandabschnitt, der den Körperhohlraum begrenzt, zu erleichtern; und
wobei der erste und der zweite der axial innen liegenden Teile relativ zueinander gleiten können, um die axiale Länge des mittleren Bereichs (24) zu reduzieren, wenn sich die Spreizkörperabschitte (20, 22) unter positiver Fixierung der ersten und zweiten Enden (34, 36) radial in diesen angreifenden Zustand expandieren, um so eine im wesentlichen konstante axiale Länge des Spreizkörpers (16) während der radialen Expansion aufrechtzuerhalten.

2. Vorrichtung nach Anspruch 1, bei der:
jeder der Spreizkörperabschnitte (20, 22) eine Konstruktion offener Webart von in einer Helix gewickelten Fäden (18) aus einem federnd nachgiebigen, körperkompatiblen Material ist.

3. Vorrichtung nach Anspruch 2, weiterhin enthaltend:
eine Einrichtung zum Fixieren des ersten Endes (34) und des zweiten Endes (36) am Gewebewandabschnitt.

4. Vorrichtung nach Anspruch 3, bei der:
die Spreizkörperabschnitte (20, 22) flexibel sind und den gegebenen ersten Durchmesser und die erste axiale Länge dann haben, wenn sie keiner äußeren Kraft unterworfen sind, und elastisch auf den zweiten Durchmesser komprimierbar sind.

5. Vorrichtung nach Anspruch 4, b i der:
di Fixiereinrichtung in n erst n und in n zw iten sich nach außen rw it rnd n äußeren Endt il des rsten bzw. des zweiten außen lieg nden Bereichs (30, 32) umfaßt, wodurch das rste und das zweit End (34, 36) größere Durchmesser hab n als den ersten Durchmesser, bei dem der Spreizkörper (16) sich in entspanntem Zustand befindet.

6. Vorrichtung nach Anspruch 5, bei der:
die Durchmesser des ersten und des zweiten Endes (34, 36) um wenigstens 5 % größer sind als der erste Durchmesser.

7. Vorrichtung nach Anspruch 6, bei der:
die axiale Lange jedes der sich erweiternden äußeren Endteile kleiner ist als ein Drittel der axialen Länge des ihm jeweils zugeordneten Spreizkörperabschnitts (20, 22).

8. Vorrichtung nach Anspruch 4, bei der:
die Fixierungseinrichtung elastische verstärkende Stränge umfaßt, die entlang dem ersten und dem zweiten äußeren Endteile einschließlich des ersten bzw. des zweiten Endes (34, 36) mit den Fäden verbunden sind.

9. Vorrichtung nach Anspruch 3, bei der:
die Fixiereinrichtung eine erste und eine zweite Anzahl von Fixierungshaken umfaßt, die am Spreizkörper (16) am ersten Ende (34) bzw. am zweiten Ende (36) montiert sind.

10. Vorrichtung nach Anspruch 1, weiterhin enthaltend:
ein langgestrecktes, flexibles und im wesentlichen nicht ausdehnbares Glied, das axial verläuft und mit dem ersten und dem zweiten Spreizkörperabschnitt (20, 22) nahe am ersten bzw. am zweiten Ende (34, 36) zum Konstanthalten der axialen Länge des Spreizkörpers (16) während der radialen Expansion verbunden ist.

Revendications

1. Dispositif se fixant dans une cavité corporelle, comprenant :
un expanseur (16) comprenant des premier et second segments sensiblement tubulaires et coaxiaux d'expanseur tressé ouvert (20, 22) emboîtés à coulissement le long de première et seconde parties respectives axialement intérieures qui se chevauchent l'une l'autre pour former une région médiale (24) de l'expanseur (16), lesdits s gments d'expanseur (20, 22) comprenant par ailleurs des première et seconde régions r spectives axial ment xtéri ures (30, 32) qui n se ch vauchent pas t qui compr nnent d s première t seconde extrémités respectiv s t

opposé s (34, 36) de l'expanseur (16) ;

lesdits s gments d' xpanseur (20, 22) ayant au moins le long desdites parties axialem nt intérieures un pr mier diamètre prédéterminé et une première longueur axiale prédéterminée, lesdits segments d'expanseur (20, 22) étant radialement compressibles à un second diamètre inférieur audit premier diamètre et à une seconde longueur axiale plus grande que ladite première longueur axiale afin de faciliter une insertion axiale dudit expanseur (16) dans une cavité corporelle afin de le mettre en un emplacement sélectionné le long de cette dernière et de fixer ensuite l'expanseur (16) l'intérieur de la cavité par mise en application des segments d'expanseur (20, 22) contre un segment de paroi de tissu délimitant ladite cavité corporelle ;

et lesdites première et seconde parties axialement intérieures étant capables de coulisser l'une par rapport à l'autre pour réduire la longueur axiale de ladite région médiale (24) lorsque lesdits segments d'expanseur (20, 22) se dilatent pour être mis à ladite application avec fixation positive desdites première et seconde extrémités (34, 36) de façon à conserver une longueur axiale sensiblement constante dudit expanseur (16) pendant ladite expansion radiale.

2. Dispositif selon la revendication 1, dans lequel chacun desdits segments d'expanseur (20, 22) est un ouvrage tressé ouvert de filaments (18) enroulés en hélice d'une matière résiliente, compatible avec le corps.

3. Dispositif selon la revendication 2, comprenant par ailleurs un moyen de fixation desdites première et seconde extrémités (34, 36) audit segment de paroi de tissu.

4. Dispositif selon la revendication 3, dans lequel lesdits segments d'expanseur (20, 22) sont flexibles et ont un premier diamètre et une première longueur axiale prédéterminés lorsqu'ils ne sont pas soumis à une force extérieure et ils sont compressibles élastiquement audit second diamètre.

5. Dispositif selon la revendication 4, dans lequel lesdits moyens de fixation consistent en des première et seconde parties extrêmes extérieures évasées desdites première et seconde régions axialement extérieures (30, 32), respectivement, lesdites première et seconde extrémités (34, 36) ayant des diamètr s supérieurs audit pr mier diamètre lorsqu l' xpans ur (16) est à l'état d relâchement.

6. Dispositif selon la revendication 5, dans lequel l s diamètres desdites premièr et s conde extrémités (34, 36) sont supérieurs audit pr mier diamètre d'au moins cinq pour cent.

7. Dispositif selon la revendication 6, dans lequel la longueur axiale de chacune desdites parties extrêmes extérieures évasées est inférieure à un tiers de la longueur axiale de celui des segments (20, 22) dudit expanseur qui lui est associé.

8. Dispositif selon la revendication 4, dans lequel ledit moyen de fixation consiste en des fils élastiques d'armature reliés auxdits filaments le long desdites première et seconde parties extrêmes extérieures qui comprennent lesdites première et seconde extrémités (34, 36), respectivement.

9. Dispositif selon la revendication 3, dans lequel ledit moyen de fixation consiste en des premier et second groupes de plusieurs crochets de fixation montés sur l'expanseur (16) auxdites première et seconde extrémités (34, 36), respectivement.

10. Dispositif selon la revendication 1, comprenant par ailleurs un élément allongé souple et pratiquement inextensible, orienté axialement et relié auxdits premier et second segments d'expanseur (20, 22) à proximité desdites première et seconde extrémités (34, 36) pour maintenir la longueur axiale de l'expanseur (16) à une valeur constante pendant ladite expansion radiale.

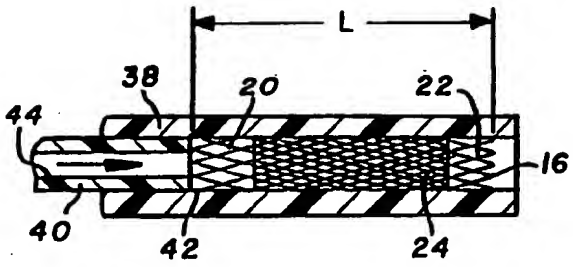


FIG.2

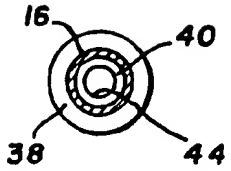


FIG.3

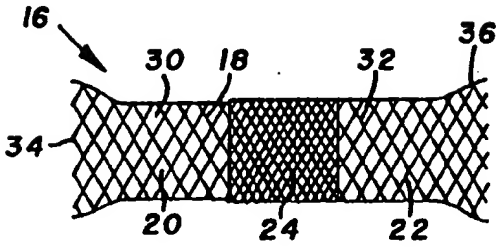


FIG.1

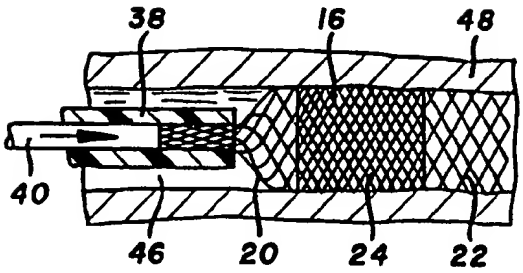


FIG.4

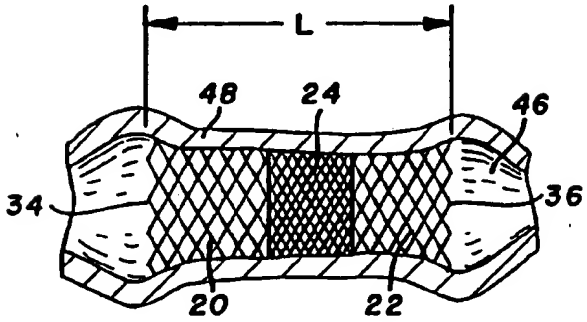
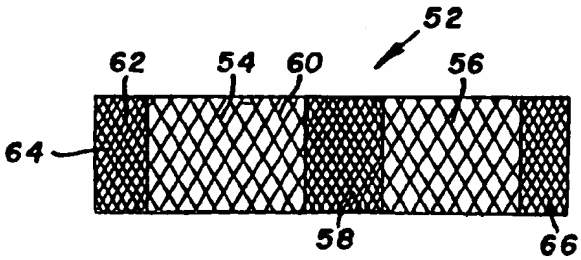


FIG.5

FIG.6



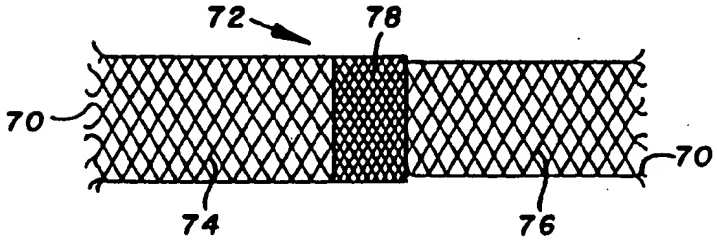


FIG.7

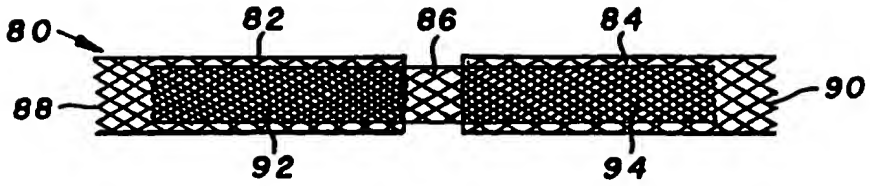


FIG.8

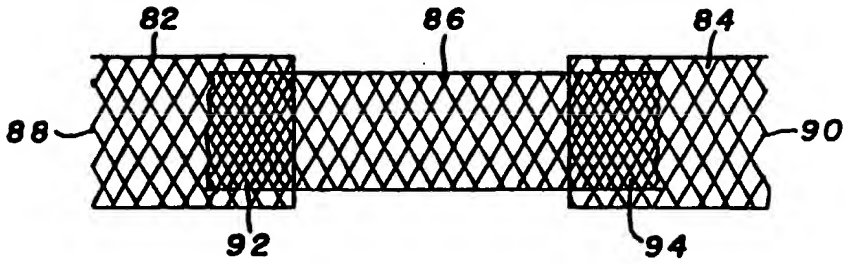


FIG.9

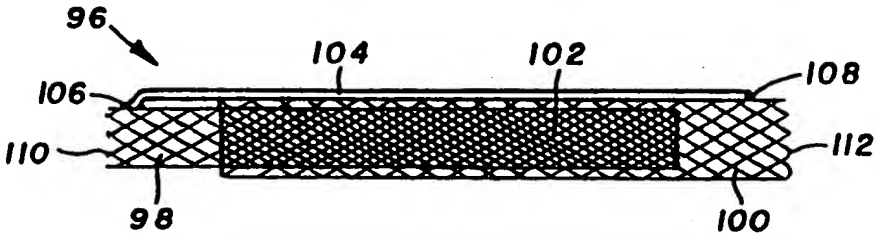


FIG.10

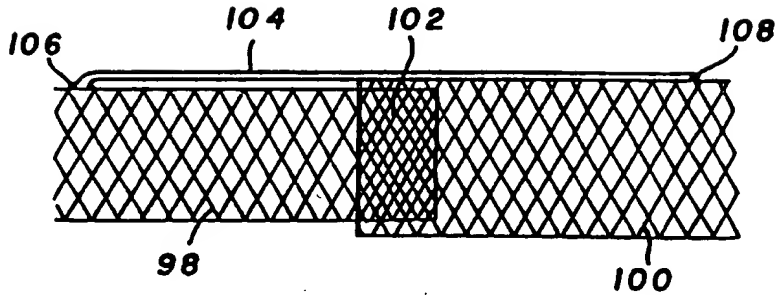


FIG.11